

Feasibility of a Multi-Level School Intervention for LGBTQ Youth  
NCT04041414

Study Protocol and Statistical Analysis Plan

September 17, 2019

## 12. Methods and Procedures - Prospective Studies

- 12.1.

**Describe in detail the design and methodology of the study. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. If applicable, include information on stratification or randomization plans. Include the frequency and duration of each activity and the total length of subject participation.**

The proposed study is intended to rigorously test the Proud & Empowered! (P&E) program in a small RCT. Feasibility will be established through a small delayed intervention RCT with four high schools in Pasadena Unified School District. Schools will be randomly assigned to an intervention or control condition. LGBTQ participants in the intervention schools will participate in P&E, whereas those attending control schools will complete only survey measures during the study, and will receive a delayed administration of the intervention in the second semester.

School-wide survey procedures: At the school level, measures of school climate will be obtained at the end of both semesters. PUSD has agreed to the following procedures as this matches their existing practice. Homeroom teachers will conduct the school-wide survey with their students toward the end of the first semester and again during the last week of school. Teachers will receive an information sheet to share information about the study. Students will be informed that they are not required to complete the survey and their responses will be anonymous. Surveys will be conducted using computers so skip logic can be incorporated and responses are better protected from view.

LGBTQ Youth Procedures: For LGBTQ P&E participants, measures (including minority stress, mental health, substance use) will be obtained at the beginning of the school year (September), after the intervention period, and at the conclusion of the school year (May). The coordinator and school counselors will make verbal presentations, distribute fliers, and have direct and confidential meetings to identify LGBTQ youth to be part of the study. Potential LGBTQ youth participants will receive a detailed assent/consent form outlining the study goals, objectives, benefits, and possible risks. Participants will be informed that their school will be randomly selected to serve as either a current or delayed intervention site. USC study staff will present adolescents with information sheets and obtain informed consent from those aged 18 or older. Next, each LGBTQ participant will create a unique identification code that will be used in the participant's survey entries to link successive data points. Surveys will be self-administered on tablets. The school counselor at the study site will track participant names and unique identifiers to keep track of the number of sessions attended by students (dosage), and school staff will not have access to participant data from surveys. Youth who turn 18 during the study will complete an informed consent.

10-week intervention procedures: Further intervention details can be found in "supporting documents" at the end of this application (Section 40.1). The 10-week protocol includes an introductory and data collection session, then sessions on Stress and Coping, Disclosure, Families, Peers and Friendship, School-related Stress, Spirituality/Religion, Social Justice, Health and Wellness, and a final Celebration and data collection session. Each session runs about 45 minutes and will be co-facilitated by a school counselor and an MSW-level USC study staff. No data other than session attendance (dosage) and the confidential surveys will be collected during the intervention.

POL Allies Procedures: A brief survey at the beginning of the year will be used to identify popular opinion leader (POL) allies who will participate in the school climate advocacy portion of the intervention. To identify POL allies, school surveys will ask students to list the names of five students in their school whom they respect, look up to, and consider good leaders. All surveys will be anonymous, so we will have no information about nominated students beyond their names and there will be no way to link nominated students to other identifying information, nor to the person(s) who nominated them. Other than the biostatistician, PI, and school counselor, no one will know the identity of the nominated individuals. The top 20 nominated POLs will be contacted by the school counselor and screened for interest in participating in the school climate portion of the program. This screening will assess each student's willingness to operate as an effective LGBTQ ally (e.g., willingness to provide visible support for LGBTQ students), and students who are not interested, for any reason (related to topic or otherwise) will not be asked to participate. The counselor will then randomly choose 10 of the identified students who expressed interest in participation, to further protect youth confidentiality. Students who report interest to the school counselor and are chosen for participation will provide assent (or consent if they are 18+), similar to the process described for LGBTQ youth.

School climate intervention procedures: The GLSEN SHINE intervention is a student leadership and advocacy intervention training program. The training will be facilitated by GLSEN staff and is completed over two one-hour sessions. It includes modules on: 1. Team Building, 2. Exploring LGBTQ+ Issues, and 3. Creating Change in Your Community. LGBTQ youth who are part of the P&E intervention will take part in this training, as will those youth identified through the POL process. After the training, ongoing intervention planning/organizing sessions (about 45 minutes each, once or twice per month, as needed) will be facilitated by the school counselor and USC study staff focused on planning the school climate project chosen during the SHINE training, for example, a "Breaking the Silence" event or a "Safe Schools Summit." Youth will work with the school counselor and USC study staff as frequently as is needed to implement the chosen activities. No data will be collected during this portion of the intervention.

The study activities will occur at the school during school hours. The intervention and POL activities will be scheduled at different times and days so that students will not miss the same class every week.

- 12.2.

**Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable.**

The biostatistician (Mamey) will assist with data management and preliminary analyses using SPSS version 24. Data will be stored on password-protected computers and in locked offices, accessible only to study staff. Univariate analyses will be run to assess variable distributions (including means, standard deviations, skewness, and kurtosis), patterns of correlations and covariance, and checks for multicollinearity and singularity to facilitate the identification of multivariate outliers and to check assumptions of multivariate normality. These statistics will be used to broadly examine the characteristics of the sample population, including demographics, minority stress, behavioral health, and school climate. Variables will be transformed as needed to reduce the effects of valid outliers or violations of multivariate normality.
- Outcome Measure Analysis Plan: Outcome analyses will be conducted using Mplus v. 7.11, using a multi-level framework to allow for students (within-level) to be nested within schools (between-level) to account for the correlated residual variance among children within a school. The analysis plan focuses on three sets of data. First, we describe in detail the impact of P&E on the adolescents that participate in the program. Next, we examine preliminary evidence for change in school climate, including attitudes and behaviors related to LGBTQ victimization, among all students in the four school sites. Finally, we examine changes in minority stress and behavioral health outcomes among all LGBTQ students in the four schools, and then use path analyses to determine whether associations between intervention condition and behavioral health outcomes are mediated (partially or fully) by minority stress.